DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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April 2, 2015

KJ Meditech Co., Ltd.
C/O Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
2651 East Chapman Avenue, Suite 110
Fullerton, California 92831

Re: K150060
Trade/Device Name: J2A Dental Implant System, J2C Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: March 02, 2015
Received: March 06, 2015

Dear Ms. Chung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang -S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K150060

Device Name

J2A Dental Implant System, J2C Dental Implant System

Indications for Use *(Describe)*

The J2A Dental Implant System and J2C Dental Implant System are indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The J2A Dental Implant System and J2C Dental Implant System are for single and two stage surgical procedures. These systems are intended for delayed loading.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

(k150060)

This summary of 510(K) – substantial equivalence information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 04/02/2015

1. Submitter

	Submitter
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2. U.S Agent/Contact Person

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3. Device

- Trade Name: J2A Dental Implant System
  J2C Dental Implant System
- Common Name: Dental Implant System
- Classification Name: Endosseous Dental Implant
- Product Code: DZE, NHA
- Classification regulation: 21CFR872.3640

4. Predicate Device:

- Primary Predicate Device:
  HERO II Dental Implant System by KJ Meditech Co., Ltd. (K121047)
- Reference Predicate Devices:
  TS Fixture System by OSSTEM IMPLANT CO.,LTD (K121995)
  GS III SYSTEM by OSSTEM IMPLANT CO.,LTD (K091208)

5. Description:

The J2A Dental Implant System and J2C Dental Implant System are internal hexagon type dental implant systems made of Titanium 6AL 4V ELI alloy intended to be surgically placed in the bone of the upper or lower jaw arches for loading after a conventional healing period. The implants may be used to replace one or more missing teeth. The systems are similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics. The surface of these systems have been treated with R.B.M (Resorbable Blast Media). The size information is as below.

J2A Dental Implant System
• 3.75mm Dia. x 7mm(L) / 8.5mm (L) / 10.0mm(L) / 11.5mm(L) / 13.0mm(L) / 15mm(L) • 4.00mm Dia. x 7mm(L) / 8.5mm (L) / 10.0mm(L) / 11.5mm(L) / 13.0mm(L) / 15mm(L) • 4.30mm Dia. x 7mm(L) / 8.5mm (L) / 10.0mm(L) / 11.5mm(L) / 13.0mm(L) / 15mm(L) • 4.50mm Dia. x 7mm(L) / 8.5mm (L) / 10.0mm(L) / 11.5mm(L) / 13.0mm(L) / 15mm(L) • 5.00mm Dia. x 7mm(L) / 8.5mm (L) / 10.0mm(L) / 11.5mm(L) / 13.0mm(L) / 15mm(L) • 5.50mm Dia. x 7mm(L) / 8.5mm (L) / 10.0mm(L) / 11.5mm(L) / 13.0mm(L) / 15mm(L) • 6.00mm Dia. x 7mm(L) / 8.5mm (L) / 10.0mm(L) / 11.5mm(L) / 13.0mm(L) / 15mm(L)
J2C Dental Implant System
• 3.75mm Dia. x 7mm(L) / 8.5mm (L) / 10.0mm(L) / 11.5mm(L) / 13.0mm(L) / 15mm(L) • 4.00mm Dia. x 7mm(L) / 8.5mm (L) / 10.0mm(L) / 11.5mm(L) / 13.0mm(L) / 15mm(L) • 4.30mm Dia. x 7mm(L) / 8.5mm (L) / 10.0mm(L) / 11.5mm(L) / 13.0mm(L) / 15mm(L) • 4.50mm Dia. x 7mm(L) / 8.5mm (L) / 10.0mm(L) / 11.5mm(L) / 13.0mm(L) / 15mm(L) • 5.00mm Dia. x 7mm(L) / 8.5mm (L) / 10.0mm(L) / 11.5mm(L) / 13.0mm(L) / 15mm(L) • 5.50mm Dia. x 7mm(L) / 8.5mm (L) / 10.0mm(L) / 11.5mm(L) / 13.0mm(L) / 15mm(L) • 6.00mm Dia. x 7mm(L) / 8.5mm (L) / 10.0mm(L) / 11.5mm(L) / 13.0mm(L) / 15mm(L)

There are one-piece abutments which are compatible with both J2A and J2C fixtures with the following features. Only straight abutments are provided.

Material / Surface Treatment	Ti 6Al 4V ELI, ASTM F136 / TiN Coating
Dimensions	• Diameter: Ø4mm ~ Ø7mm • Cuff: 1mm~5mm • Height: 4.0mm~7.0mm • Connection platform: Narrow platform & Wide platform

There are also two-piece abutments which are compatible with both J2A and J2C fixtures with the following features. Only straight abutments are provided.

Material / Surface Treatment	Ti 6Al 4V ELI, ASTM F136 / TiN Coating
Dimensions	• Diameter: Ø4mm ~ Ø7mm • Cuff: 1mm~5mm • Height: 4.0mm~7.0mm • Connection platform: Narrow platform & Wide platform

Cover screws made of Titanium 6AL 4V ELI alloy are also provided both for J2A and J2C fixtures.

6. Indication for use:

The J2A Dental Implant System and J2C Dental Implant System are indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The J2A Dental Implant System and J2C Dental Implant System are for single and two stage surgical procedures. These systems are intended for delayed loading.

7. Basis for Substantial Equivalence

7.1. Fixtures and Cover Screws

The J2A Dental Implant and J2C Dental Implant have the same intended use as the identified predicate devices. They are similar in fundamental scientific technology in that they are all threaded, root form implants constructed of titanium with RBM roughened surfaces. They all share same internal hexagon abutment connection system with internal beveled interface. The subject and predicate devices are both bone-level implants that share similar body shape design such as straight walled neck and tapered body design.

The manufacturing facility, raw materials, materials for the surface treatments (RBA treatment), surface treatment method, manufacturing process, and cleaning process of the J2A and J2C Dental Implant are identical to the predicate device (Hero I and IS Dental Implant System, K121047).

Item	Subject Device (Modified Device 1)	Subject Device (Modified Device 2)	Primary Predicate Device (Unmodified Device)	Reference Predicate Device 1	Reference Predicate Device 2
510(K) Number	K150060	K150060	K121047	K121995	K091208
Device Name	J2A Dental Implant System	J2C Dental Implant System	HERO II Dental Implant System	TS Fixture System	GS III SYSTEM
Manufacturer	KJ Meditech Co., Ltd.	KJ Meditech Co., Ltd.	KJ Meditech Co., Ltd.	OSSTEM IMPLANT CO.,LTD	OSSTEM IMPLANT CO.,LTD
Indications for Use	The J2A Dental Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained,	The J2C Dental Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or	The HERO II Dental Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained,	The TS Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations,	The GS III System is indicated for use in partially or fuhlly edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdent-ure restorations, and terminal or intermediate abutment support for fixed bridgework.

	screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The J2A Dental Implant System is for single and two stage surgical procedures. The system is intended for delayed loading.	overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The J2C Dental Implant System is for single and two stage surgical procedures. The system is intended for delayed loading.	screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The HERO II Dental Implant System is for single and two stage surgical procedures. The system is intended for delayed loading.	and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. TS Fixture System is compatible with abutment in the ET/SS Implant System.	The GS II System is for single and two stage surgical procedures. It is not for immediate load.
Design	• Implant Type: Bone Level Implant • Connection Type: Internal Hexagon • Neck Design: Straight walled neck • Body Design: Tapered design	• Implant Type: Bone Level Implant • Connection Type: Internal Hexagon • Neck Design: Straight walled neck with micro-thread • Body Design: Tapered design	• Implant Type: Bone Level Implant • Connection Type: Internal Hexagon • Neck Design: Straight walled neck • Body Design: Tapered design	• Implant Type: Bone Level Implant • Connection Type: Internal Hexagon • Neck Design: Straight walled neck • Body Design: Tapered design	• Implant Type: Bone Level Implant • Connection Type: Internal Hexagon • Neck Design: Straight walled neck with micro-thread • Body Design: Tapered design
Appearance					
Endosseous Implant Material	Ti 6Al 4V ELI, ASTM F136	Ti 6Al 4V ELI, ASTM F136	Ti 6Al 4V ELI, ASTM F136	Grade 4 Pure Titanium (ASTM F67)	Grade 4 Pure Titanium (ASTM F67)
Surface Treatment	RBM Treatment	RBM Treatment	RBM Treatment	SA Treatment	SA Treatment

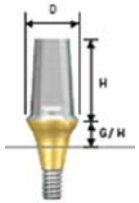
Sterilization Method	Same – No modification	Same – No modification	Gamma	Gamma	Gamma
Implant Diameters	3.75mm, 4.0mm, 4.3mm, 4.5mm, 5.0 mm, 5.5mm, 6.0mm	3.75mm, 4.0mm, 4.3mm, 4.5mm, 5.0 mm, 5.5mm, 6.0mm	3.75mm, 4.0mm, 4.5mm, 5.0 mm, 6.0mm	3.75mm, 3.77mm, 4.2mm, 4.25mm, 4.6mm, 4.63mm, 4.65mm, 5.05mm, 5.08mm, 5.1mm	3.75mm ~5.1mm
Implant Lengths	7.0mm – 15.0 mm	7.0mm – 15.0 mm	8.5mm – 15.0 mm	7.0mm - 15.0 mm	7.0 – 15.0 mm
Cover Screw	 Ti 6Al 4V ELI, ASTM F136		 Ti 6Al 4V ELI, ASTM F136	 Ti 6Al 4V ELI, ASTM F136/Anodizing	-

7.2. Abutments

The J2A and J2C Abutments have the same intended use as the identified predicate devices. They are similar in fundamental scientific technology and design. The subject and the predicate devices offer one-piece as well as two-piece type abutments.

The manufacturing facility, raw materials, materials for the surface treatments (TiN coating), surface treatment method, manufacturing process, and cleaning process of the J2A and J2C Abutments are identical to the predicate device (Hero I and IS Dental Implant System, K121047).

Item	Subject Device (Modified Device)	Primary Predicate Device (Unmodified Device)	Reference Predicate Device
510(K) Number	K150060	K121047	K121995
Device Name	J2A and J2C Dental Implant System	HERO II Dental Implant System	TS Fixture System

Manufacturer	KJ Meditech Co., Ltd.	KJ Meditech Co., Ltd.	OSSTEM IMPLANT CO.,LTD
Indications for Use	The J2A and J2C Dental Implant Systems are indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The J2A and J2C Dental Implant Systems are for single and two stage surgical procedures. The system is intended for delayed loading.	The HERO II Dental Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The HERO II Dental Implant System is for single and two stage surgical procedures. The system is intended for delayed loading.	The TS Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. TS Fixture System is compatible with abutment in the ET/SS Implant System.
One Piece Abutment	 ▪ Ti 6Al 4V ELI, ASTM F136 / TiN Coating (Entire body) ▪ Diameter: Ø4mm ~ Ø7mm Cuff: 1mm~5mm Height: 4.0mm~7.0mm	 ▪ Ti 6Al 4V ELI, ASTM F136 / TiN Coating (Partial) ▪ Diameter: Ø4mm ~ Ø6mm Cuff: 1mm~4mm Height: 4.0mm~7.0mm	 ▪ Ti 6Al 4V ELI, ASTM F136 / TiN Coating (Partial) ▪ Diameter: Ø4mm ~ Ø7mm Cuff: 1mm~5mm Height: 4.0mm~7.0mm

Two Piece Abutment	 ▪ Ti 6Al 4V ELI, ASTM F136 / TiN Coating (Entire body) ▪ Diameter: Ø4mm ~ Ø7mm Cuff: 1mm~5mm Height: 4.0mm~7.0mm	 ▪ Ti 6Al 4V ELI, ASTM F136 / TiN Coating (Entire body) ▪ Diameter: Ø4mm ~ Ø7mm Cuff: 1mm~4mm Height: 4.0mm~7.0mm	 ▪ Ti 6Al 4V ELI, ASTM F136 / TiN Coating (Entire body) ▪ Diameter: Ø4mm ~ Ø7mm Cuff: 1mm~5mm Height: 4.0mm~7.0mm

8. Non-Clinical Testing

Risk analysis was conducted according to ISO14971 to demonstrate that the following modifications to the company's own predicate, *Hero II Dental Implant System* (K121047) is substantially equivalent:

- Fixture thread design change
- Fixture size addition
- Coating area expansion for one-piece type abutments
- Abutment size addition

Additional predicate devices of similar design and dimensions were identified to determine substantial equivalence. In addition, based on the risk analysis the shelf-life, sterilization, biocompatibility, and performance testing of the predicate, *Hero II Dental Implant System* (K121047), is applicable to the subject device.

9. Conclusion

The subject devices and the predicate device have the same intended use and have the same technological characteristics. The subject and predicate implants are all made of commercially pure titanium and have the same surface treatments.

Overall, the J2A Dental Implant system and the J2C Dental Implant system have the following similarities to the predicate device:

* have the same intended use,
* use the same operating principle,
* incorporate the same basic design,
* incorporate the same material and the surface treatment.

Based on the similarities, we conclude that the J2A Dental Implant system and the J2C Dental Implant system are substantially equivalent to the predicate devices.